



[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Request for Comment: Input on Recommendations from the Council of Councils

Working Group on Use of Chimpanzees in NIH-Supported Research

SUMMARY: The National Institutes of Health (NIH) Council of Councils received and adopted the recommendations and Report of the NIH Council of Councils Working Group on the Use of Chimpanzees in NIH-Supported Research on January 22, 2013. The report is posted on the NIH website at http://dpcpsi.nih.gov/council/working_group_message.aspx. The agency will consider the recommendations contained in the report as the agency formulates policy. The NIH also announces the opening of a Request for Comment (RFC) period to collect input on the recommendations from interested parties. Comments will be accepted until Saturday, March 23, 2013, via the comment database at <http://grants.nih.gov/grants/rfi/rfi.cfm?ID=31>. In the interim, NIH will continue to apply its policy on Research Involving Chimpanzees (see NOT-OD-12-025; <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-12-025.html>).

DATE: Responses to this RFC will be accepted through 11:59 pm EST Saturday, March 23, 2013.

ADDRESS: All comments should be submitted electronically to
<http://grants.nih.gov/grants/rfi/rfi.cfm?ID=31>.

FOR FURTHER INFORMATION CONTACT: The Division of Program
Coordination, Planning, and Strategic Initiatives, Office of the Director, National
Institutes of Health at dpcpsi@od.nih.gov.

SUPPLEMENTARY INFORMATION: The use of animals in biomedical and
behavioral research has enabled scientists to identify new ways to treat illness, extend
life, and improve health and well-being. Chimpanzees are our closest relatives in the
animal kingdom, providing exceptional insights into human biology and requiring
special consideration and respect. While used very selectively and in limited numbers
for biomedical research, chimpanzees have served an important role in advancing
human health in the past. However, new methods and technologies developed by the
biomedical community have provided alternatives to the use of chimpanzees in several
areas of research.

In December 2010, the NIH commissioned a study by the Institute of Medicine
(IOM) to assess whether chimpanzees are or will be necessary for NIH-funded
biomedical and behavioral research. A year later on December 15, 2011, the IOM
issued its findings, with a primary recommendation that the use of chimpanzees in

research be guided by a set of principles and criteria. The committee proposed three principles to analyze current and potential future research using chimpanzees:

1. That the knowledge gained must be necessary to advance the public's health;
2. There must be no other research model by which the knowledge could be obtained, and the research cannot be ethically performed on human subjects;
and
3. The animals used in the proposed research must be maintained either in ethologically appropriate physical and social environments (i.e., as would occur in their natural environment) or in natural habitats.

Based on its deliberations, the IOM committee concluded that “while the chimpanzee has been a valuable animal model in past research, most current use of chimpanzees for biomedical research is unnecessary.” The committee generated case studies of predominant areas of chimpanzee research exemplifying the committee’s vision for applying the criteria it developed. The case studies concluded that the following areas of the research they assessed may continue to require the use of chimpanzees: some ongoing research on monoclonal antibody therapies, research on comparative genomics, and important studies of social and behavioral factors that affect the development, prevention, or treatment of disease. The committee was unable to reach consensus on the necessity of the chimpanzee for the development of prophylactic hepatitis C virus vaccine. It also acknowledged that new, emerging, or re-emerging diseases may present challenges that may require the use of chimpanzees.

To assist the NIH in considering future requests to use chimpanzees in research, the IOM committee provided the set of principles and criteria as a framework to guide NIH's assessment.

In December 2011, NIH accepted the IOM Recommendations (<http://www.nih.gov/news/health/dec2011/od-15.htm>) contained in the report *Chimpanzees in Biomedical and Behavioral Research: Assessing the Necessity* and issued interim policy in notice NOT-OD-12-025, which indicated that NIH would not fund any new or other competing projects (renewal and revisions) for research involving chimpanzees and will not allow any new projects to go forward with NIH-owned or -supported chimpanzees. However, currently funded research was allowed to continue. The policy remains in effect until NIH considers and issues policy implementing the IOM recommendations.

NIH assembled a working group of the NIH Council of Councils on February 1, 2012, to provide advice on implementation of the IOM recommendations and to consider the size and placement of the active and inactive populations of NIH-owned or -supported chimpanzees. The Working Group was charged with (1) Developing a plan for implementation of the IOM's guiding principles and criteria; (2) Analyzing currently active NIH-supported research using chimpanzees to advise on which studies currently meet the principles and criteria defined by the IOM report and to advise on the process for closing studies if any do not comply with the IOM recommendations; (3) Advising on the size and placement of active and inactive populations of NIH-owned or -supported chimpanzees that may need to be considered as a result of

implementing the IOM recommendations; and (4) Developing a review process for considering whether potential future use of the chimpanzee in NIH-supported research is scientifically necessary and consistent with the IOM principles.

The Working Group's efforts culminated in the report containing 28 recommendations to NIH. In developing its recommendations, the Working Group considered public comments received in response to a previous Request for Information (http://dpcpsi.nih.gov/council/working_group.aspx#Summary), considered the scientific use of chimpanzees in currently funded research, obtained advice from external experts, and visited several facilities that house and care for chimpanzees. The Working Group submitted its recommendations and the report to the NIH Council of Councils in open session on January 22, 2013, and the Council of Councils adopted the report. The report is available at http://dpcpsi.nih.gov/council/working_group_message.aspx.

Comments Requested: The NIH is seeking input on the recommendations from the Council of Councils from the public and the biomedical research community, including foundations, scientific societies, government and regulatory agencies, industry, and NIH grantee institutions. Input is sought for each of the report's recommendations. Response to this RFC is voluntary. Responders are free to address any or all of the recommendations.

Please note that the government will not pay for response preparation or for the use of any information contained in the comments. The NIH may make all comments

available, including name of the responder. In addition, NIH may prepare and make available a summary of all input received that is responsive to this RFC.

How to Submit a Response: All comments should be submitted electronically to <http://grants.nih.gov/grants/rfi/rfi.cfm?ID=31>. Comments should pertain to the specific recommendation for which feedback is requested and should conform to the word limit indicated. You will see an electronic confirmation acknowledging receipt of your response, but will not receive individualized feedback on any suggestions. No basis for claims against the U.S. government shall arise as a result of a response to this request for information or from the government's use of such information.

Dated: January 28, 2013

Lawrence A. Tabak,

Principal Deputy Director

National Institutes of Health

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